

REMARKS

The Office Action dated February 10, 2003 presents the examination of claims 1, 3-9, 16-18, 21-23, and 31-34. Claim 35 is withdrawn from consideration. Claims 3 and 4 are canceled herein. Claims 1, 5, and 35 are amended. Support for subject matter added to the claims is found in former claim 4 and in the specification, such as on page 7, lines 22-23 and page 8, lines 14-19. No new matter is inserted into the application.

Claim Objections (Paragraph 1, Page 2 of the Office Action)

The Examiner objects to claim 35 under 37 C.F.R. 1.75(c) for allegedly being in improper form. Applicants respectfully traverse. Reconsideration of the claims and withdrawal of the instant objection are respectfully requested.

In order to overcome this objection, claim 35 is amended to be dependent from claim 22 only and the subject matter of claim 1 and former claim 4 is inserted into claim 35.

Rejection under 35 U.S.C. § 112, first paragraph (Paragraph 2, Pages 2-3 of the Office Action)

The Examiner rejects claims 1, 3-9, 16-18, 21-23, and 31-34 under 35 U.S.C. § 112, first paragraph for allegedly containing subject matter not described in the specification. Claims 3 and 4 are canceled, thus rendering rejection thereof moot. Applicants respectfully traverse the rejection applied to the pending claims. Reconsideration of the claims and withdrawal of the instant rejection are respectfully requested.

Specifically, the Examiner asserts that the specification does not describe the alleged "wide genus" of species which qualify as "acid macromolecular substances that do not serve as templates." In order to overcome this rejection, but not to acquiesce to the Examiner's position, Applicants amend claim 1 to list the water-soluble acidic macromolecular substances formally recited in claim 4 and to recite that when the water-soluble acid macromolecular substance is a DNA, said DNA does not serve as a template. Support for this amendment is found on page 7, lines 22-23 of the specification.

Applicants respectfully submit that the claims recite subject matter which is adequately described in the specification such that the requirements of 35 U.S.C. § 112, first paragraph are met.

Withdrawal of the instant rejection is therefore respectfully requested.

Rejection under 35 U.S.C. § 102 (Paragraphs 4-5, Pages 3-4 of the Office Action)

The Examiner makes the following rejections under 35 U.S.C. § 102(b) :

(1) Claims 1 and 3-9 over Blakely '162 (U.S. Patent 5,418,162);

(2) Claims 1, 3-9, and 16-17 over Chetverin '478 (U.S. Patent 5,616,478);

(3) Claims 1, 3-4, 16-18, 21-22, and 23 over Koster '906 (U.S. Patent 5,928,906);

(4) Claims 1, 3-8 over Barton '556 (U.S. Patent 5,225,556);
and

(5) Claims 1, 3-4, 16-18, and 21 over Sorge '772 (U.S. Patent 5,556,772).

Claims 3 and 4 are canceled, thus rendering rejections thereof moot. Applicants respectfully traverse the rejections applied to the pending claims. Reconsideration of the claims and withdrawal of the instant rejections are respectfully requested.

None of the references cited specifically teach a "DNA

synthesis reaction-enhancer." Rather, they teach various components of PCR or dideoxynucleotide sequencing.

Specifically, Blakely '162 teaches the use of heparin sulfate for blocking a filter in which DNAs to be analyzed are immobilized during filter hybridization. According to the attached *Molecular Cloning*, 2nd eds., 9.48-9.50 (attached hereto as Exhibit 1) and *Nucleic Acids Research* 12: 5637 (1984) (attached hereto as Exhibit 2), lines 6-7 and the like, it can be deduced that the heparin sulfate of Blakely '162 prevents non-specific adsorption of nucleic acid probes to filters instead of heparin. Therefore, Blakely '162 neither discloses nor suggests the enhancement of a DNA synthesis reaction by heparin sulfate during DNA synthesis.

Chetverin '478 discloses nucleic acid amplification in solid media, as described in column 6, lines 47-52. Thus, the PCR reaction is carried out in an immobilized media rather than in solution. As recited in the amended claims 1 and 35, water-soluble acidic macromolecular substances are utilized in the present invention as disclosed on page 8, lines 14-19 of the specification. In the portion of Chetverin '478 referenced by the Examiner, polyacrylamide, alginate, and carrageenan are disclosed as examples of solid supports. Therefore, Chetverin '478 neither discloses nor suggests the enhancement of a DNA synthesis reaction by

polyacrylamide, alginate, or carrageenan during DNA synthesis. From this viewpoint, the present invention could not be achieved by the disclosure of Chetverin '478.

Koster '906 and Sorge '772 disclose nucleic acid amplification carried out in the presence of Mg^{2+} and two polymerases. However, while Mg^{2+} is a cofactor essential for strand extension by DNA polymerase, the Mg^{2+} is not a complex ion as used in the present invention, or a complex ion is not formed therewith. Therefore, neither Koster '906 nor Sorge '772 disclose or suggest the enhancement of a DNA synthesis reaction by Mg^{2+} during DNA synthesis.

Finally, Barton '556 discloses a method for labeling, nicking, and cleaving DNA on the basis of intercalation to a DNA strand, and DNA cleavage ability of a cobalt(III) complex and rhodium(III) complex having a phenanthroline backbone. The present invention is distinguishable from Barton '556 in that a cationic complex exhibiting the ability to enhance a DNA synthesis reaction is used as described on page 10, lines 4-22 of the specification. Specifically, the transition metal complex may be any complex capable of exhibiting an action of enhancing DNA synthesis. For this reason, Barton '556 fails to anticipate the present invention.

Rejection under 35 U.S.C. § 103 (Paragraphs 8-9, Pages 5-7 of the Office Action)

The Examiner rejects claims 18 and 21 under 35 U.S.C. § 103(a) for allegedly being unpatentable over Chetverin '478 in view of Sorge '772, and claims 31-34 over Sorge '772 in view of Gaugler '437 (U.S. Patent 5,512,437). Applicants respectfully traverse. Reconsideration of the claims and withdrawal of the instant rejection are respectfully requested.

As noted above, neither Chetverin '478 nor Sorge '772 disclose a DNA reaction-enhancer. Thus, claims 18-21 are not obvious over Chetverin '478 in view of Sorge '772. Gaugler '437 fails to make up for the deficiencies of Sorge '772. Specifically, Gaugler '437 merely discloses a PCR kit. Gaugler '437 also fails to disclose a DNA reaction-enhancer as encompassed by the present claims. For these reasons, claims 31-34 are not obvious over Sorge '772 in view of Gaugler '437.

Conclusion

Applicants respectfully submit that the above remarks and/or amendments to the instant claims fully address and properly overcome, render moot, or otherwise accommodate all of the pending rejections/objections of record. All of the present claims define


patentable subject matter such that this application should be placed into condition for allowance. Early and favorable action on the merits of the present application is thereby requested.

Should there be any outstanding matters that need to be resolved in the present application, the Examiner is respectfully requested to contact Kristi L. Rupert, Ph.D. (Reg. No. 45,702) at the telephone number of the undersigned below, to conduct an interview in an effort to expedite prosecution in connection with the present application.

If necessary, the Commissioner is hereby authorized in this, concurrent, and future replies, to charge payment or credit any overpayment to Deposit Account No. 02-2448 for any additional fees required under 37 C.F.R. § 1.16 or under 37 C.F.R. § 1.17; particularly, extension of time fees.

Respectfully submitted,

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Attachments: Exhibit 1
Exhibit 2